IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

MERCK, SHARP & DOHME CORP.,

Plaintiff,

v.

ACTAVIS LABORATORIES FL, INC., ANDRX CORPORATION, ACTAVIS PHARMA, INC. and ACTAVIS, INC.,

Defendants.

Civil Action No 15-6075 (PGS-DEA)

Electronically Filed

MEMORANDUM IN SUPPORT OF DEFENDANT ACTAVIS, INC.'S MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION

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TABLE OF AUTHORITIES

			Page
I.	INT	RODUCTION	1
II.	FAC	TUAL BACKGROUND OF THE TEVA TRANSACTION	2
III.	LEG	AL STANDARDS	4
	A.	IT IS MERCK'S BURDEN TO PROVE THAT SUBJECT MATTER JURISDICTION EXISTS OVER ALLERGAN FINANCE	4
	B.	§ 271(e) EXISTS TO CONFER DECLARATORY JUDGMENT JURSIDCTION IN HATCH-WAXMAN CASES	4
	C.	DECLARATORY JUDGMENT JURISDICTION ONLY EXISTS WHERE THERE IS A CASE OR CONTROVERSY BETWEEN THE PARTIES	5
IV.	THERE IS NO CASE OR CONTROVERSY BETWEEN ALLERGAN FINANCE AND MERCK6		
	A.	ALLERGAN'S DIVESTITURE OF THE POSACONAZOLE ANDA EXTINGUISHES THE JURISDICTION CONFERRED BY § 271(e)	7
	В.	MONETARY DAMAGES UNDER § 271(e) ARE ONLY AVAILABLE AGAINST A PARTY WHICH COMMERCIALIZES AN INFRINGING PRODUCT	9
	C.	EVEN UNDER MERCK'S INTERPRETATION, THERE STILL EXISTS NO SUBJECT MATTER JURISDICTION OVER ALLERGAN FINANCE	10
	D.	THE STIPULATION CANNOT CONFER JURISDICTION, BECAUSE SUBJECT MATTER JURISDICTION CANNOT BE CREATED BY AGREEMENT	13
V.	CON	NCLUSION	14

TABLE OF AUTHORITIES

Case	Page(s)
Abbott Labs. v. Roxane Labs., Inc., No. CIV.A. 12-457-RGA, 2013 WL 2322770 (D. Del. May 28, 2013)	6
Allergan v. Alcon Labs., Inc., 324 F.3d 1322 (Fed. Cir. 2003)	5
Already, LLC v. Nike, Inc., 133 S. Ct. 721 (2013)	7, 9
Aktiebolag v. Andrx Pharm., Inc., 695 F. Supp. 2d 21 (S.D.N.Y. 2010)	10
Benitec Australia, Ltd. v. Nucleonics, Inc., 495 F.3d 1340 (Fed. Cir. 2007)	5
Ben Venue Labs., Inc. v. Novartis Pharm. Corp., 146 F.Supp.2d 572 (D. N.J. 2001)	14
Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc., 527 F.3d 1278 (Fed. Cir. 2008)	6
Celgene Corp. v. Teva Pharms, USA, Inc., 412 F.Supp.2d 439 (D. N.J. 2006)	10, 12
CNA v. United States, 535 F.3d 132 (3d Cir. 2008)	5
Eli Lilly Co. v. Medtronic, Inc., 496 U.S. 661 (1990)	5, 10
Glaxo Grp. Ltd. v. Apotex, Inc., 376 F.3d 1339 (Fed. Cir. 2004)	6
Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562 (Fed. Cir. 1997)	9
Janssen Pharamceutica, N.V. v. Apotex, Inc., 540 F.3d 1353 (Fed. Cir. 2008)	13
MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118 (2007)	6, 14
Momenta Pharms., Inc. v. Amphastar Pharms, Inc., 686 F.3d 1348 (Fed. Cir. 2012)	11
Prasco, LLC v. Medicis Pharm. Corp., 537 F.3d 1329 (Fed. Cir. 2008)	9, 13

Spectacor Mgmt. Grp. v. Brown, 131 F.3d 120 (3d Cir. 1997)	13
Spencer v. Kemna, 523 U.S. 1 (1998)	
Statutes, Rules and Regulations	
35 U.S.C. § 271(e)(2)	passim
35 U.S.C. § 271(e)(4)	passim
Fed. R. Civ. P. 12(b)(1)	5

Defendant Actavis, Inc. (now known as Allergan Finance, LLC ("Allergan Finance") submits this memorandum of law in support of its motion to dismiss all claims against it in the above-captioned action, pursuant to Federal Rule of Civil Procedure 12(b)(1).

Defendants Actavis Laboratories FL, Inc., Andrx Corporation, and Actavis Pharma, Inc. (collectively, the "Teva Defendants"), consent to this motion, which, if granted, would not affect their procedural standing in this case. Plaintiff Merck Sharp & Dohme Corp. ("Merck") opposes this motion. For the reasons stated below, Allergan Finance respectfully requests that its motion be granted.

I. INTRODUCTION

This is a Hatch-Waxman action based on the submission of Abbreviated New Drug Application No. 207355 (the "Posaconazole ANDA"). At the time the Posaconazole ANDA was submitted, the Teva Defendants were subsidiaries of Defendant Actavis, Inc., and all Defendants were part of the Allergan corporate family.

A sea change occurred in August 2016. That is when Teva acquired the Teva Defendants, along with all right, title, and interest to the Posaconazole ANDA. Defendant Actavis, Inc. remained with the Allergan corporate family and changed its name to Allergan Finance, LLC. Following the Teva transaction, Allergan Finance now has no interest in the Posaconazole ANDA, and will not be involved in the marketing, distribution, or sale of any ANDA product relating from the Posaconazole ANDA. Accordingly, there is no longer any case or controversy between Plaintiff Merck and Defendant Allergan Finance.

Soon after the Teva acquisition was completed, Plaintiff Merck was informed of the acquisition of the Teva Defendants and the Posaconazole ANDA by Teva, and that Allergan Finance no longer had any interest in the Posaconazole ANDA. Despite the transfer of the ANDA-in-suit to Teva, Merck is refusing to dismiss Actavis, Inc. from the case.

Merck contends that subject matter jurisdiction persists because, prior to the divestiture, Actavis, Inc. stipulated to infringement under 35 U.S.C. § 271(e)(2) along with the Teva Defendants. Specifically, Merck reads 35 U.S.C. § 271(e)(4)(C) as creating liability for any entity that participates in the filing of an ANDA that describes an infringing product, even if that entity never engages in any act that would give rise to damages, including the commercial manufacture, use, offer to sell, or sale within the U.S. Merck's argument is nonsensical for at least three reasons. First, infringement under 35 U.S.C. § 271(e)(2) through the filing of an ANDA is a technical, jurisdiction-conferring act of infringement for which there is no remedy once the ANDA has been divested. Second, Merck's interpretation would result in Allergan Finance being liable for future infringing acts of completely independent third parties, over whom it has no control. Third, even if Merck's interpretation is correct, such liability is too speculative to confer jurisdiction as it would require three things to happen: (1) the Teva Defendants launch at risk; (2) the patentin-suit is held not invalid; and (3) the Teva Defendants are not able to satisfy any damages claim. This series of events may or may not occur, and so even under Merck's interpretation, there cannot be any current case or controversy.

Accordingly, Allergan Finance should be dismissed from this action.

II. FACTUAL BACKGROUND OF THE TEVA TRANSACTION

When this litigation commenced, Actavis, Inc. was the parent company of the Teva Defendants. *See* D.I. 17, Defendants' Corporate Disclosure Statement, at ¶¶ 2-3. Actavis, Inc. was itself a wholly-owned subsidiary of Allergan plc. *Id.* at ¶ 4. In August, 2016, the Teva Defendants were transferred to Teva, along with other subsidiaries engaged in the generic pharmaceutical business. Allergan retained certain assets and subsidiaries, including Actavis, Inc., which subsequently adopted the name Allergan Finance. (Declaration of Brian

Anderson ("Anderson Decl."), at ¶¶ 3-5.) All right and title to the Posaconazole ANDA was divested to Teva as part of the transaction, along with many other ANDAs. (*Id.* at ¶¶ 6, 8.) As a result, Allergan Finance no longer has any interest in the Posaconazole ANDA or the Teva Defendants, directly or indirectly. Nor does Allergan Finance have any plans or ability to be involved in the further development, distribution, or marketing of the Teva Defendants' ANDA products. (*Id.* at ¶ 6.)

As part of the Teva agreement, Teva assumed all liabilities of Allergan's generics business, including those arising after the closing. This includes any theoretical damages for infringement against Allergan Finance, though none would be conceivable because Allergan Finance ceased to infringe upon the sale of its generics businesses. (*Id.* at ¶ 9; *see also* Anderson Decl. Exh. A, Master Purchase Agreement by and between Allergan plc and Teva Pharmaceutical Industries Ltd.) Following Allergan's divestiture of its generic businesses, plaintiffs in other cases have often readily agreed to remove or substitute Allergan corporate entities which no longer have any interest in the ANDA in suit.

During discovery in this action, Defendants, in an effort to narrow the issues for fact and expert discovery and trial, stipulated that the filing of the Posaconazole ANDA would constitute infringement under 35 U.S.C. § 271(e)(2) if the asserted claims of U.S. Patent No. 5,661,151 ("the '151 patent") are found valid and enforceable (the "Stipulation"). Notably, although Merck's complaint also alleged infringement under 35 U.S.C. §§ 271 (a), (b), and/or (c) if Defendants were to commercially make, use, offer to sell, sell, or import their ANDA Product before the expiration of the '151 patent, or induce or contribute to any such conduct (D.I. 1 at ¶¶ 29, C), none of the Defendants stipulated that any such conduct would constitute infringement. Further, none of the Defendants stipulated that they would be jointly or severally liable for any acts of infringement by the others. Rather, Defendants

solely stipulated to infringement under § 271(e)(2), the artificial act of infringement triggered by the submission of an ANDA. Merck's only legally cognizable injury against Allergan Finance was the filing of the Posaconazole ANDA, a harm which has been obviated by its divestiture.

III. LEGAL STANDARDS

A. IT IS MERCK'S BURDEN TO PROVE THAT SUBJECT MATTER JURISDICTION EXISTS OVER ALLERGAN FINANCE

A complaint may be dismissed at any point during the litigation for lack of subject matter jurisdiction. Fed. R. Civ. P. 12(b)(1). Where a defendant files a Rule 12(b)(1) motion to dismiss a factual attack on the existence of subject matter jurisdiction, it is the burden of the plaintiff to prove that there is a case or controversy between the parties. *CNA v. United States*, 535 F.3d 132, 145 (3d Cir. 2008). *See also Benitec Australia, Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1345 (Fed. Cir. 2007) ("The burden of bringing forth such further information may logically rest with the party challenging jurisdiction...but the actual burden of proof remains with the party seeking to invoke jurisdiction.") (internal citations omitted). The district court may consider extrinsic evidence beyond the pleadings which are decisive to determining whether jurisdiction exists over the matter. *CNA*, 535 F.3d at 145 (citing *U.S. ex rel. Atkinson v. Pa. Shipbuilding Co.*, 473 F.3d 506, 514 (3d Cir. 2007)).

B. § 271(e) EXISTS TO CONFER DECLARATORY JUDGMENT JURSIDCTION IN HATCH-WAXMAN CASES

As the Supreme Court has explained, § 271(e) establishes jurisdiction for the federal district courts in Hatch-Waxman litigation through "the creation of a highly artificial act of infringement that consists of submitting an ANDA…" *Eli Lilly Co. v. Medtronic, Inc.*, 496 U.S. 661, 677 (1990). *See also Allergan v. Alcon Labs., Inc.*, 324 F.3d 1322, 1330 (Fed. Cir. 2003) ("In short, section 271(e)(2) makes it possible for the district court to exercise its section 1338(a) jurisdiction in the situation in which an ANDA has been filed."). As a

result, the Federal Circuit has interpreted § 271(e)(2) as "primarily a jurisdictional-conferring statute that establishes a case or controversy in a declaratory judgment action." *Glaxo Grp. Ltd. v. Apotex, Inc.*, 376 F.3d 1339 (Fed. Cir. 2004).

C. DECLARATORY JUDGMENT JURISDICTION ONLY EXISTS WHERE THERE IS A CASE OR CONTROVERSY BETWEEN THE PARTIES

The federal district courts retain declaratory judgment jurisdiction in Hatch-Waxman cases "only to the extent that they present an Article III case or controversy." Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc., 527 F.3d 1278, 1290 (Fed. Cir. 2008). To maintain an action, a party must demonstrate that "the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 127 (2007) (internal citations omitted). "This means that, throughout the litigation, the plaintiff 'must have suffered, or be threatened with, an actual injury traceable to the defendant and likely to be redressed by a favorable judicial decision." Spencer v. Kemna, 523 U.S. 1, 7 (1998) (quoting Lewis v. Cont'l Bank Corp., 494 U.S. 472, 477-78 (1990)) (emphasis added). This requirement must be met at all times while the case is being litigated. "If, during the litigation, the plaintiff's claim no longer amounted to a case or controversy under Article III, its case would be moot." Abbott Labs. v. Roxane Labs., Inc., No. CIV.A. 12-457-RGA, 2013 WL 2322770, at *4 (D. Del. May 28, 2013) (citing *Spencer*, 523 U.S. at 7).

The Supreme Court has reiterated that, once a party's activities no longer implicate the other's legal rights, jurisdiction ceases to exist. "A case becomes moot—and therefore no longer a 'Case' or 'Controversy' for purposes of Article III – 'when the issues presented are no longer 'live' or the parties lack a legally cognizable interest in the outcome.... [T]he

case is moot if the dispute 'is no longer embedded in any actual controversy about the plaintiffs' particular legal rights." *Already, LLC v. Nike, Inc.*, 133 S. Ct. 721, 726 (2013).

IV. THERE IS NO CASE OR CONTROVERSY BETWEEN ALLERGAN FINANCE AND MERCK

Despite Merck's knowledge that Allergan Finance no longer has any connection to the Posaconazole ANDA or the Teva Defendants, it has refused to agree to dismiss Defendant Actavis, Inc., now Allergan Finance, from the present action. As a threshold matter, courts routinely allow substitution or withdrawal of parties in Hatch-Waxman cases once, as here, it becomes clear that the party no longer has any interest in the underlying ANDA, and no plans to be involved with the marketing, distribution, or sale of the ANDA products. Merck's refusal to voluntarily dismiss Allergan Finance is contrary not only to standard practice in Hatch-Waxman litigation, but is without support in the case law. No jurisdiction over Allergan Finance can be sustained and it should be dismissed from this action.

Merck incorrectly contends that the stipulation requires Allegan Finance to be liable for damages if the Teva Defendants were to launch "at-risk," relying on a tortured reading of 35 U.S.C. § 271(e)(4)(C) to support its theory of subject matter jurisdiction. While the statute does allow for damages stemming from the commercial manufacture, use, offer to sell, sale, or importation of an ANDA product, such liability can only incur against a party which has actually *itself* undertaken such activities. Merck bases its refusal to dismiss on a purely novel interpretation which would require an innocent third party to be liable for damages because of the conduct of another, wholly unrelated corporation.

Moreover, Merck's position underscores its lack of any legally cognizable interest against Allergan Finance – *even if* Merck's reading were the correct one, it *still* would not give rise to jurisdiction over Allergan Finance. Of course, if the Teva Defendants launched

at risk, Merck would be entitled to full compensation from the Teva entities if the patent-insuit was held not invalid. But such a launch is speculative at this time, and this conjecture
alone cannot suffice to establish jurisdiction over Allergan Finance. Moreover, any right
against Allergan Finance would only be relevant if the Teva Defendants could not satisfy
such a hypothetical judgment. But Teva is one of the largest pharmaceutical companies in
the world. As a result, Merck's position relies on a chain of conjecture, speculation which
cannot possibly establish that a case or controversy currently exists between Merck and
Allergan Finance.

A. ALLERGAN'S DIVESTITURE OF THE POSACONAZOLE ANDA EXTINGUISHES THE JURISDICTION CONFERRED BY § 271(e)

Merck's argument underlying its refusal to consent to dismissal, that Allergan Finance would be liable for damages should the Teva Defendants launch at risk, is unsupported in the case law, and fundamentally misconstrues the extent of the jurisdiction conferred by § 271(e). Even assuming, *arguendo*, that the Teva Defendants were to launch at risk, under no circumstance would Merck have any recourse against Allergan Finance, a wholly-unrelated third party, for their potential infringement.

As discussed above, Merck can only continue this action against Allergan Finance if there is subject matter jurisdiction, and there is only subject matter jurisdiction if a legally cognizable case or controversy between the parties exists throughout all stages of a litigation. But federal jurisdiction under § 271(e)(2) provides an artificial case or controversy only to the extent necessary for the courts to hear litigation arising under the Hatch-Waxman Act. "Section 271(e)(2) provide[s] patentees with a defined act of infringement sufficient to create case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning infringement and validity." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997). Indeed, as a result of the divestiture of the Posaconazole ANDA, there is

no longer any dispute between Merck and Allergan Finance. Thus, where, as here, the ANDA that gave rise to the litigation has been transferred, there is no longer any artificial act of infringement, and the jurisdictional hook over the ANDA filer conferred by § 271(e)(2) must too be extinguished. *See Already*, 133 S.Ct. at 732 ("Already's only legally cognizable injury...is now gone and...cannot reasonably be expected to recur. There being no other basis on which to find a live controversy, the case is clearly moot.")

Merck's contention that there remains a case or controversy between it and Allergan Finance is specious. To demonstrate a controversy of "sufficient immediacy and reality to create a justiciable controversy," Merck must allege "(1) an injury in fact, i.e. a harm that is concrete and actual or imminent, not conjectural or hypothetical, (2) that is fairly traceable to the defendant's conduct, and (3) redressable by a favorable decision." *Prasco, LLC v. Medicis Pharm.* Corp., 537 F.3d 1329, 1338 (Fed. Cir. 2008) (internal quotations omitted). But Merck can prove *none* of these three elements. First, as discussed in further detail in Sec. IV.C, below, the only injury identified by Merck – monetary damages stemming from a possible at-risk launch by the Teva Defendants – is *purely* conjectural and hypothetical at this juncture. Moreover, it would be unrelated to any conduct by Allergan Finance, which has divested the Posaconazole ANDA and will not be involved in the marketing, distribution, or sale of the Teva Defendants' ANDA products.

Finally, there is no remedy now against Allergan Finance which could redress any injury suffered by Merck. That is because, as the Supreme Court has acknowledged, the remedies available under § 271(e)(4) rely on the ANDA filer continuing to prosecute its application. "Not only is the defined act of infringement artificial, so are the specified consequences." *Eli Lilly*, 496 U.S. at 677. Because Hatch-Waxman Act litigation concerns a product which has not yet launched, the patentee's typical remedy is delay of FDA

approval until patent expiration, or injunctive relief precluding commercialization of the ANDA product. *Id.* (citing 35 U.S.C. § 271(e)(4)). But while these may suffice to redress the harm caused to a patentee by the launch of a competing generic product, there is no conduct of Allergan Finance's which these remedies could cure.

Thus, because Allergan Finance ceased to "infringe" upon the divestiture of the Posaconazole ANDA, there is no case or controversy between Merck and Allergan Finance.

B. MONETARY DAMAGES UNDER § 271(e) ARE ONLY AVAILABLE AGAINST A PARTY WHICH COMMERCIALIZES AN INFRINGING PRODUCT

Merck's reliance on § 271(e)(4)(C) to find a continuing injury and establish subject matter jurisdiction over Allergan Finance is fundamentally improper. As a threshold matter, this damages provision cannot alone confer jurisdiction. "As is clear from the statute, subsection 271(e)(4)(C) is not an independent basis for a claim." Aktiebolag v. Andrx Pharm., Inc., 695 F. Supp. 2d 21, 27 (S.D.N.Y. 2010). Moreover, although monetary damages are available in Hatch-Waxman cases, they can only be pursued against a party that has engaged in the commercial acts of infringement, such as commercial manufacture, use or sale, not an unrelated third party. The plain language of the provision explains that damages "may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States ..." 35 U.S.C. § 271(e)(4)(C) (emphasis added); see also Celgene Corp. v. Teva Pharms, USA, Inc., 412 F.Supp.2d 439, 445 (D. N.J. 2006) (distinguishing actual infringement from the jurisdiction-conferring provision of § 271(e)(2)). Thus, there can be no jurisdiction over a party which has ceased to "infringe" through divestiture of the infringing ANDA, and plays no part in the commercialization of the ANDA product.

That monetary damages under § 271(e) are only available against a party which itself

commercializes an ANDA product is further supported by Congress's implantation of the safe harbor provisions. As the statute makes clear, it is not an act of infringement to make, use, offer to sell, sell, or import a patented invention "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." 35 U.S.C. § 271(e)(1). "Congress could not have been clearer in its choice of words: as long as the use of the patented invention is solely for uses 'reasonably related' to developing and submitting information pursuant to 'a Federal law' regulating the manufacture, use, or sale of drugs, it is not 'an act of infringement." *Momenta Pharms., Inc. v. Amphastar Pharms, Inc.*, 686 F.3d 1348, 1354-55 (Fed. Cir. 2012). Thus, a party which develops, but does not market, an ANDA product does not infringe and cannot be liable for any damages caused by another's commercialization.

In sum, because Allergan Finance has divested its ANDA, it no longer "infringes" and cannot commit any acts giving rise to a remedy under § 271(e). Because it no longer has any connection to the Teva Defendants, Allergan Finance would not be liable for any damages stemming from § 271(e)(4)(C). No controversy exists between Allergan Finance and Merck to establish subject matter jurisdiction in this action, and Actavis, Inc. should be dismissed.

C. EVEN UNDER MERCK'S INTERPRETATION, THERE STILL EXISTS NO SUBJECT MATTER JURISDICTION OVER ALLERGAN FINANCE

As discussed above, neither Actavis, Inc.'s past conduct, nor any future acts by the Teva Defendants constitute infringement on behalf of Allergan Finance. Merck, instead, improperly attempts to use the stipulation to bootstrap jurisdiction in this action. But even if Merck were correct, and the stipulation *could* create liability against Allergan Finance for the conduct of the Teva Defendants, this does not currently give rise to subject matter

jurisdiction over Allergan Finance. The possibility of Allergan Finance's *potential future liability* is not nearly of sufficient immediacy and reality to constitute a justiciable case or controversy.

Merck relies on the potential for monetary damages as its justification for refusing to voluntarily dismiss Allergan Finance from this case. But the statute clearly distinguishes the artificial infringement triggered by § 271(e) from any infringement stemming from commercial use; the purpose of the Hatch-Waxman Act "is to permit the matter to be decided before the drug goes to market and *an actual, rather than artificial, act of infringement occurs.*" *Celgene*, 412 F.Supp.2d at 445 (emphasis added) (holding that the mere filing of an ANDA can never constitute willful infringement). Indeed, commercialization of the products described in the Posaconazole ANDA has not occurred and in fact *could not* occur until the lifting of the 30-month stay in, which expires in December, 2017.

Under Merck's position, it could only, theoretically, have a legitimate interest against Allergan Finance if (1) Teva Defendants do in fact launch at-risk; (2) the patent-in-suit is held not invalid; and (3) the Teva Defendants – subsidiaries of one of the largest pharmaceutical companies in the world – cannot alone satisfy any judgment against them. This hypothetical chain of events which may or may not occur cannot possibly be the sufficiently concrete threat of harm required for the federal courts to exercise jurisdiction. It is a "bedrock rule that a case or controversy must be based on a *real* and *immediate* injury or threat of future injury that is *caused by the defendants*—an objective standard that cannot be met by a purely subjective or speculative fear of future harm." *Prasco*,537 F.3d at 1339 (emphasis in original). At this juncture, the possibility of the Teva Defendants launching at risk in more than ten months is neither real nor immediate – and nor would it be caused by

Allergan Finance. Merck's basis for jurisdiction is conjecture about what *might* transpire in nearly a year, and does not nearly suffice to establish a current case or controversy or give rise to jurisdiction over Allergan Finance.

In fact, the Federal Circuit has held specifically that disputes stemming from the potential future timing of the launch of a generic drug are not of sufficient immediacy as to confer case-or-controversy jurisdiction. In Janssen Pharamceutica, N.V. v. Apotex, Inc., 540 F.3d 1353 (Fed. Cir. 2008), Apotex contended that there was a sufficient Article III controversy to support its counterclaims for invalidity of unasserted patents where such invalidity could hasten the launch of its own generic. There, Teva was the first filer, and consequently enjoyed a 180-day exclusivity period before Apotex could bring a competing generic risperidone product to market; Apotex contended that it would be harmed if Teva were to delay the launch of its generic risperidone product. *Id.* at 1362. But Apotex filed its counterclaims more than two years before Teva could launch its generic product; the counterclaims were dismissed more than six months before Teva could have launched. Id. The Federal Circuit explained that "[a]t no time between the filing of the counterclaims through the final judgment was there any basis to conclude that Teva will, or is likely to, delay in bringing its generic product to market in the future." *Id.* at 1363. The court concluded that "a possible delay in the future of a first Paragraph IV ANDA filer in launching its generic product does not give rise to declaratory judgment jurisdiction." Id.

The same reasoning applies against resting jurisdiction solely on a possible at-risk launch by the Teva Defendants. Merck's speculation concerning the timing of the launch of Teva Defendants' generic product is far too attenuated to create the necessary substantial controversy of sufficient immediacy to warrant the issuance of subject matter jurisdiction against Allergan Finance. *See also MedImmune*, 549 U.S. at 127. This is especially true

because the statutory scheme underlying the 30-month stay in Hatch-Waxman cases is designed to allow for resolution of the action before the generic drug goes to market, thus limiting the possibility of at-risk launches. "It is important to remember that the purpose of the 30-month stay is...to create an adequate window of time during which to litigate the question of whether a generic will infringe the patented product, without actually having to introduce the generic product to the market." *Ben Venue Labs., Inc. v. Novartis Pharm.*Corp., 146 F.Supp.2d 572, 579 (D. N.J. 2001).

Therefore, even Merck's own position supports dismissal unless and until the Teva Defendants launch their ANDA product at risk – an event that is at this time merely hypothetical.

D. THE STIPULATION CANNOT CONFER JURISDICTION, BECAUSE SUBJECT MATTER JURISDICTION CANNOT BE CREATED BY AGREEMENT

Finally, that Merck rests its argument on a stipulation – especially one that does not itself accede to liability for Allergan Finance based on future acts by the Teva Defendants – further demonstrates the deficiency in its position. Significantly, Merck ignores that no party can stipulate to jurisdiction where there would be none. "Of course, we do not mean to suggest that parties can agree to the jurisdiction of a federal court and thereby confer jurisdiction that would not otherwise exist. That is clearly not the case. Federal jurisdiction arises under the constitution. It is not created by contract or waiver." *Spectacor Mgmt. Grp. v. Brown*, 131 F.3d 120, 125 (3d Cir. 1997). Thus, even if Merck's interpretation of § 271(e)(4)(C) was correct, and Allergan Finance *could* be liable for any judgment unsatisfied by the Teva defendants, *at best* the statute would confer subject matter jurisdiction at such time as there is an at-risk launch, with damages. That time has not yet occurred. This lack of immediacy further establishes the lack of any current justiciable case or controversy

between it and Allergan Finance.

V. CONCLUSION

For the reasons enumerated above, Allergan Finance respectfully requests that all claims against it in the instant action be dismissed.

Dated: February 10, 2017

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